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Confirmation No.: 9324

Filed: 24 July 2003

For: DENTAL WHITENING COMPOSITIONS AND METHODS

Remarks

The Office Action mailed 19 July 2005 has been received and reviewed. No claims having been added, canceled, or amended, the pending claims are claims 1-80. Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection under 35 U.S.C. §102

The Examiner rejected claims 1-5, 8-11, 14-19, 22, 30-34, 36-48, and 50-80 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,312,668 (Mitra et al.). Applicants respectfully traverse the rejection.

"[F]or anticipation under 35 U.S.C. 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02 (emphasis added). To properly anticipate a claim under 35 U.S.C. § 102, a reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention "without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 455 F.2d 586, 587, 172 U.S.P.Q. 524, 526 (C.C.P.A. 1972) (emphasis added). Applicants respectfully submit that Mitra et al. fail to teach every aspect of the present claims without any need for picking, choosing, and combining the various disclosures therein.

Mitra et al.

Mitra et al. disclose "[c]oatings for hard tissue and surfaces of the oral environment . . . that reduce adhesion of bacteria and proteinaceous substances to these surfaces. Methods of reducing adhesion of these materials to such surfaces, and polymers for incorporation into such coatings are also provided" (abstract).

Mitra et al. further disclose that "[t]he coating of the present invention comprises a vinylic copolymer having repeat units of A, B and C, where A is derived from an ethylenically unsaturated monomer containing at least one polar or polarizable group, B is derived from an

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ethylenically unsaturated monomer optionally containing modifying groups and C is derived from an ethylenically unsaturated organosiloxane chain" (column 3, lines 41-47). "The polymer may also contain one or more crosslinkable groups for later fixing of the coating or surface composition by a subsequent crosslinking reaction after the polymer has been placed on the intended substrate" (column 10, lines 26-29).

Mitra et al. further state that "[w]hen the polymers of the present compositions comprise pendant ethylenically unsaturated moieties that can be reacted in a subsequent step after application to the intended substrate, the compositions also comprise a polymerization catalyst to effect reaction of the ethylenically unsaturated group. Such catalyst may comprise a photoinitiation catalyst or the combination of an oxidizing agent and a reducing agent" (column 16, lines 53-60).

Mitra et al. further describe photoinitiators. "The photoinitiator frequently can be used alone but typically it is used in combination with a suitable donor compound or a suitable accelerator (for example, amines, peroxides, phosphorus compounds, ketones and alpha-diketone compounds)" (column 17, lines 1-5). "The photoinitiator should be present in an amount sufficient to provide the desired rate of photopolymerization. . . . Typically, the photoinitiator components will be present at a total weight of about 0.01 to about 5%, more preferably from about 0.1 to about 5%, based on the total weight (including water) of the unset coating components" (column 17, lines 24-31).

Mitra et al. further describe alternative polymerization initiators. "Alternative polymerization initiators include redox systems, which are a combination of a reducing agent and an oxidizing agent" (column 17, lines 32-34). "Preferred oxidizing agents include cobalt (III) chloride, tert-butyl hydroperoxide, ferric chloride, hydroxylamine (depending upon the choice of reducing agent), perboric acid and its salts, and salts of a permanganate or persulfate anion. Hydrogen peroxide can also be used, although it has been found to interfere with the photoinitiator in some instances. The amount of reducing agent and oxidizing agent should be sufficient to provide the desired degree of polymerization of the ethylenically-unsaturated

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component. The preferred amount for each of the reducing agent and oxidizing agent is about 0.01 to about 10%, more preferably about 0.02 to about 5%, based on the total weight (including water) of the components" (column 17, lines 52-65).

However, Mitra et al. fail to specifically disclose a dental whitening composition suitable for coating oral surfaces. Specifically, Mitra et al. disclose the use of polymerization catalysts with polymers that include pendant ethylenically unsaturated moieties. Although not explicitly identified as such by Mitra et al., some of the polymerization catalysts (e.g., hydrogen peroxide) could arguably be whitening agents if used at sufficient levels. However, Applicants respectfully submit that Mitra et al. fail to clearly and unequivocally disclose the presently claimed combinations of polymers and whitening agents as described herein below.

Applicants note that the Examiner pointed to column 17, lines 52-58 of Mitra et al. for a disclosure of "hydroperoxide and optionally hydrogen peroxide" (page 2 of the Office Action mailed 19 July 2005). Applicants wish to clarify that while "tert-butyl hydroperoxide" and "hydrogen peroxide" are clearly disclosed as oxidizing agents by Mitra et al. (e.g., column 17, lines 52-58), Mitra et al. fail to explicitly recite "hydroperoxide" *per se* as alleged by the Examiner.

THE PRESENT CLAIMS**Claims 1-5, 46, and 53-56**

Claims 1-5 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and a polymer that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride releasing group, with the proviso that *the polymer does not include pendant ethylenically unsaturated moieties*. Claim 46 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 1; and claims 53-56 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 1.

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Mitra et al. lack, among other things, a clear and unequivocal disclosure of the combination of *a tooth whitening agent* and a *polymer that does not include pendant ethylenically unsaturated moieties*. Although Mitra et al. disclose polymerization catalysts (e.g., hydrogen peroxide, which could arguably be a whitening agent if used at sufficient levels) for use with *polymers that include pendant ethylenically unsaturated moieties*, Mitra et al. provide no teaching or suggestion of using such polymerization catalysts with a *polymer that does not include pendant ethylenically unsaturated moieties*.

Thus, for at least this reason, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 1-5, 46, and 53-56.

Claims 8-11, 14, 47, and 57-60

Claims 8-11 and 14 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and a polymer that includes a repeating unit including a polar or polarizable group, and *a repeating unit including a fluoride releasing group*. Claim 47 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that include a dental whitening composition as recited in claim 8; and claims 57-60 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 8.

Mitra et al. lack, among other things, a clear and unequivocal disclosure of a composition that includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and a polymer that includes a repeating unit including a polar or polarizable group, and *a repeating unit including a fluoride releasing group*.

First, as discussed in the traverse of the rejection of claims 1-5, 46, and 53-56 herein above, although not explicitly identified as such by Mitra et al., some of the polymerization catalysts disclosed by Mitra et al. (e.g., hydrogen peroxide) could arguably be whitening agents if used at sufficient levels. However, one of skill in the art would be required to pick and choose

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from the list of exemplary photoinitiators (e.g., column 17, lines 6-23) and redox systems (e.g., column 17, lines 47-58) to select a potential whitening agent (e.g., hydrogen peroxide) for a composition.

Second, Mitra et al. disclose that typically the photoinitiator components will be present at a total weight of about 0.01 to about 5%. Mitra et al. further disclose that for redox systems, the preferred amount for each of the reducing agent and oxidizing agent is about 0.01 to about 10%, more preferably about 0.02 to about 5%. Although hydrogen peroxide could be used as an oxidizing agent, Mitra et al. caution that it has been found to interfere with the photoinitiator in some instances. Further, Applicants respectfully submit that one of skill in the art would recognize that redox systems cure upon reaction of the oxidizing agent (e.g., hydrogen peroxide) with the reducing agent, resulting in consumption of both oxidizing and reducing agents. Thus, the amount of oxidizing agent remaining, if any, during or after cure, arguably for potential use as a whitening agent, would be substantially lower than the initial recited level. For at least these reasons, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at the presently claimed composition that includes *greater than 10% by weight of a tooth whitening agent*.

Third, although not explicitly identified as such by Mitra et al., an "A unit" derived from an ammonium monomer where the counter ion is fluoride (column 4, lines 43-60) could be a fluoride releasing group. However, one of skill in the art would be required to pick and choose from the list of "A units" disclosed by Mitra et al. (e.g., column 3, line 49 to column 5, line 12) to select a repeating unit including an ammonium monomer, and to further pick and choose fluoride from the list of counter ions (e.g., column 4, lines 57-60) to arrive at a fluoride releasing group. Thus, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at the presently claimed composition that includes *a repeating unit including a fluoride releasing group*. Applicants note that the Examiner also mentioned "fluoroacrylates" (page 3, line 2 of the Office Action mailed 19 July 2005). Although fluoroacrylates are fluorine-

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containing groups, Applicants respectfully submit that that Examiner has failed to show that such fluorine-containing groups are necessarily *fluoride releasing groups*.

Finally, Mitra et al. provide no explicit examples of a composition that includes the combination of greater than 10% by weight of a tooth whitening agent, based on the total weight of the dental whitening composition, and a polymer that includes a repeating unit including a polar or polarizable group, and a repeating unit including a fluoride releasing group.

Thus, for at least these reasons, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 8-11, 14, 47, and 57-60.

Claims 15-19, 22, 48, and 61-64

Claims 15-19 and 22 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *a tooth whitening agent* and a polymer that includes a repeating unit including a polar or polarizable group and a repeating unit including *a fluoride releasing group*, with the proviso that the dental whitening composition *does not include hydrogen peroxide*. Claim 48 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 15; and claims 61-64 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 15.

Mitra et al. lack, among other things, a clear and unequivocal disclosure of the combination of *a tooth whitening agent* and a polymer that includes a repeating unit including a polar or polarizable group and a repeating unit including *a fluoride releasing group*, with the proviso that the dental whitening composition *does not include hydrogen peroxide*.

First, as discussed in the traverse of the rejection of claims 8-11, 14, 47, and 57-60 herein above, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at the presently claimed composition that includes a repeating unit including a fluoride releasing group.

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Second, Applicants respectfully submit that Mitra et al. lack a clear and unequivocal disclosure of a dental whitening composition that does not include hydrogen peroxide. Thus, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at a dental whitening composition that does not include hydrogen peroxide.

Finally, Mitra et al. provide no explicit examples of a dental whitening composition that includes the combination of a tooth whitening agent and a polymer that includes a repeating unit including a polar or polarizable group and a repeating unit including a fluoride releasing group, with the proviso that the dental whitening composition does not include hydrogen peroxide. Thus, for at least these reasons, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 15-19, 22, 48, and 61-64.

Claims 30-34, 36, 50, and 69-72

Claims 30-34, and 36 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes a tooth whitening agent and a polymer that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof, with the proviso that *the polymer does not include pendant ethylenically unsaturated moieties*. Claim 50 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 30; and claims 69-72 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 30.

Mitra et al. lack, among other things, a clear and unequivocal disclosure of the combination of a tooth whitening agent and a *polymer that does not include pendant ethylenically unsaturated moieties*. Although Mitra et al. disclose polymerization catalysts (e.g., hydrogen peroxide, which could arguably be a whitening agent if used at sufficient levels) for use with *polymers that include pendant ethylenically unsaturated moieties*, Mitra et al. provide no

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teaching or suggestion of using such polymerization catalysts with a *polymer that does not include pendant ethylenically unsaturated moieties*.

Thus, for at least this reason, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 30-34, 36, 50, and 69-72.

Claims 37-40, 51, and 73-76

Claims 37-40 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes *greater than 10% by weight of a tooth whitening agent*, based on the total weight of the dental whitening composition, and a polymer that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane chain, a hydrophobic fluorine-containing group, and combinations thereof. Claim 51 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 37; and claims 73-76 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 37.

As discussed in the traverse of the rejection of claims 8-11, 14, 47, and 57-60 herein above, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at the presently claimed composition that includes *greater than 10% by weight of a tooth whitening agent*.

Thus, for at least this reason, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 37-40, 51, and 73-76.

Claims 41-45, 52, and 77-80

Claims 41-45 are directed to a dental whitening composition suitable for coating oral surfaces. The composition includes a tooth whitening agent and a polymer that includes a repeating unit including a polar or polarizable group, and a repeating unit including a group selected from the group consisting of a hydrophobic hydrocarbon group, a graft polysiloxane

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chain, a hydrophobic fluorine-containing group, and combinations thereof, with the proviso that the dental whitening composition *does not include hydrogen peroxide*. Claim 52 is directed to a coating on hard tissue surfaces or surfaces of the oral environment that includes a dental whitening composition as recited in claim 41; and claims 77-80 are directed to methods of whitening teeth using a dental whitening composition as recited in claim 41.

Applicants respectfully submit that Mitra et al. lack a clear and unequivocal disclosure of a dental whitening composition that does not include hydrogen peroxide. Thus, Applicants respectfully submit that picking and choosing from Mitra et al. would be required to arrive at a dental whitening composition that does not include hydrogen peroxide.

Thus, for at least this reason, Applicants respectfully submit that Mitra et al. fail to anticipate present claims 41-45, 52, and 77-80.

Claims 65-68

Claims 65-68 depend from independent claim 23, either directly or ultimately.

Applicants note that claim 23 is not under rejection as being anticipated by Mitra et al. under 35 U.S.C. §102. As such, Applicants respectfully submit that claims 65-68 are also not anticipated by Mitra et al. for at least the reasons that claim 23 is not anticipated by Mitra et al.

Further, claims 65-68 are directed to methods of whitening teeth using a dental whitening composition suitable for coating oral surfaces. The composition includes a tooth whitening agent and a polymer that includes: a repeating unit including a polar or polarizable group; and a repeating unit including a fluoride releasing group including tetrafluoroborate anions. Applicants note that the Examiner has failed to specifically identify a disclosure of a fluoride releasing group including tetrafluoroborate anions in Mitra et al. Thus, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of anticipation by Mitra et al. of claims 65-68.

In view of the remarks presented herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §102 is respectfully requested.

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Rejections under 35 U.S.C. §103

The Examiner rejected claims 6-7, 12-13, 20-21, 23-29, 49, and 65-68 under 35 U.S.C. §103(a) as being unpatentable over Mitra et al. as applied above taken with EP 0363095 (Aasen et al.). Applicants respectfully traverse the rejection.

The deficiencies of Mitra et al. as applied to independent claims 1, 8, and 15 have been discussed herein above in the traverse of the rejections of claims 1, 8, and 15 under 35 U.S.C. §102. Applicants respectfully submit that Aasen et al. provide nothing to correct the deficiencies of Mitra et al. Thus, for at least these reasons, Applicants respectfully submit that claims 6-7 (which depend from claim 1), claims 12-13 (which depend from claim 8), and claims 20-21 (which depend from claim 15) are patentable over Mitra et al. taken with Aasen et al.

Further, claims 6-7, 12-13, 20-21, 23-29, 49, and 65-68 all recite a dental whitening composition that includes a tooth whitening agent. As discussed herein above in the traverse of the rejection of claims 8-11, 14, 47, and 57-60 under 35 U.S.C. §102, picking and choosing from Mitra et al. would be required for one of skill in the art to arrive at a composition that includes a dental whitening agent at a level sufficient for the composition to be a dental whitening composition. Similarly, Applicants respectfully submit that Aasen et al. fails to provide the guidance lacking in Mitra et al. for one of skill in the art to pick and choose a dental whitening agent, and to pick and choose an appropriate level of the dental whitening agent to arrive at the presently claimed dental whitening compositions.

Thus, for at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claims 6-7, 12-13, 20-21, 23-29, 49, and 65-68 as unpatentable over Mitra et al. taken with Aasen et al.

The Examiner rejected claims 8-11, 37-40, 47, 51, 57-60, and 73-76 under 35 U.S.C. §103(a) as being unpatentable over Mitra et al. as applied above taken with U.S. Patent No. 6,312,666 (Oxman et al.). Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . there must be some suggestion or

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motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." M.P.E.P. §706.02(j). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

As motivation for combining Mitra et al. taken with Oxman et al., the Examiner stated that "[b]oth Mitra et al. and Oxman et al. are directed to oral care compositions and teach the use of a whitening agent" (page 5, lines 9-11 of the Office Action mailed 19 July 2005). Applicants respectfully disagree.

While Oxman et al. clearly teach the use of a whitening agent, Mitra et al. do not. As stated in the section herein above discussing Mitra et al., Mitra et al. fail to specifically disclose a dental whitening composition suitable for coating oral surfaces. Specifically, Mitra et al. disclose the use of polymerization catalysts with polymers that include pendant ethylenically unsaturated moieties. Although some of the polymerization catalysts (e.g., hydrogen peroxide) could arguably be whitening agents if used at sufficient levels, none of the polymerization catalysts were explicitly identified as whitening agents by Mitra et al. Thus, Applicants respectfully submit that one of skill in the art would have no motivation to combine Mitra et al. taken with Oxman et al.

Further, the Examiner alleged that "[t]he amount of a whitening agent employed is normally a matter of preference subject to routine optimization of one of ordinary skill in the art. Thus, the amount may be varied in order to obtain the result desired in the final product" (page 5, lines 11-13 of the Office Action mailed 19 July 2005). To the extent that the Examiner is alleging that the amount of whitening agent is a result-effective variable, Applicants respectfully disagree.

"A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." M.P.E.P. §2144.05(II)(B). Applicants respectfully submit that Mitra et al. did not recognize that some of

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the polymerization catalysts recited therein (e.g., hydrogen peroxide) could arguably be whitening agents if used at sufficient levels.

In contrast, Mitra et al. recite the use of hydrogen peroxide as a polymerization catalyst. For polymerization catalysts that are photoinitiators, Mitra et al. recite that "[t]ypically, the photoinitiator components will be present at a total weight of about 0.01 to about 5%, more preferably from about 0.1 to about 5%, based on the total weight (including water) of the unset coating components" (column 17, lines 24-31). For polymerization catalysts that are redox systems, Mitra et al. recite that "[t]he preferred amount for each of the reducing agent and oxidizing agent is about 0.01 to about 10%, more preferably about 0.02 to about 5%, based on the total weight (including water) of the components" (column 17, lines 52-65). Thus, Applicants respectfully submit that one of skill in the art would have no motivation to use greater than 10% by weight of a polymerization catalyst as a tooth whitening agent to arrive at a dental whitening composition as recited in present claims 8-11, 37-40, 47, 51, 57-60, and 73-76.

For at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claims 8-11, 37-40, 47, 51, 57-60, and 73-76 as unpatentable over Mitra et al. taken with Oxman et al.

The Examiner rejected claim 35 under 35 U.S.C. §103(a) as being unpatentable over Mitra et al. as applied above taken with U.S. Patent No. 4,018,732 (Lakshmanan). Applicants respectfully traverse the rejection.

The deficiencies of Mitra et al. as applied to independent claim 30 has been discussed herein above in the traverse of the rejection of claims 30-34, 36, 50, and 69-72 under 35 U.S.C. §102. Applicants respectfully submit that Lakshmanan provides nothing to correct the deficiencies of Mitra et al. Thus, for at least these reasons, Applicants respectfully submit that claim 35, which depends from claim 30, is patentable over Mitra et al. taken with Lakshmanan.

Thus, for at least this reason, Applicants respectfully submit that claim 35 is patentable over Mitra et al. taken with Lakshmanan.

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In view of the remarks presented herein, reconsideration and withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 18th day of November, 2005, at 12:28 p.m. (Central Time).

By: Name: Rachel Engelhardt-Gebhardt
